Complete Summary

GUIDELINE TITLE

National Academy of Clinical Biochemistry laboratory medicine practice guidelines: Point of care testing, oversight and administration of cardiac biomarkers for acute coronary syndromes.

BIBLIOGRAPHIC SOURCE(S)

Starrow AB, Apple FS, Wu AH, Jesse RL, Francis GS, Christenson RH, Cannon CP, Morrow DA, Newby LK, Ravkilde J, Tang W. National Academy of Clinical Biochemistry laboratory medicine practice guidelines: point of care testing, oversight, and administration of cardiac biomarkers for acute coronary syndromes. Point Care 2007 Dec;6(4):215-22.

Storrow AB, Apple FS, Francis GS. National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines: point of care testing, oversight and administration of cardiac biomarkers for acute coronary syndromes. Washington (DC): National Academy of Clinical Biochemistry; 2007. 9 p. [86 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Wu AH, Apple FS, Gibler WB, Jesse RL, Warshaw MM, Valdes R Jr. National Academy of Clinical Biochemistry Standards of Laboratory Practice: recommendations for the use of cardiac markers in coronary artery diseases. Clin Chem 1999 Jul;45(7):1104-21. [119 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Acute coronary syndrome (ACS)

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Risk Assessment

CLINICAL SPECIALTY

Cardiology
Emergency Medicine
Family Practice
Internal Medicine
Pathology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Clinical Laboratory Personnel
Emergency Medical Technicians/Paramedics
Health Care Providers
Hospitals
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To present recommendations that focus on utilization of cardiac biomarkers of cardiac injury in the emergency department (ED)
- To address organizational aspects of providing results, administrative logistics and cost-effectiveness, as well as timing needs for performance cardiac biomarkers

TARGET POPULATION

Patients with suspected or known acute coronary syndrome (ACS)

INTERVENTIONS AND PRACTICES CONSIDERED

1. Administrative logistics of cardiac biomarker services
    - Collaboration on providing cardiac biomarker measurements (stakeholders for providing cardiac biomarker services; development of accelerated protocols; quality assurance of processes)
    - Responsibility for providing and monitoring cardiac biomarker measurements (involvement of laboratory personnel in device selection, training of individuals to perform analyses, equipment

maintenance, compliance and documentation requirements by regulatory agencies)

2. Logistics of cardiac biomarker services
    - Cardiac biomarker testing: preanalytical (measurements), analytical (turnaround time) and postanalytical aspects (minimizing potential for medical error; reporting results) and need for speed

MAJOR OUTCOMES CONSIDERED

- Cardiac marker testing turnaround time (TAT)
- Effectiveness of rapid cardiac marker testing on timeliness of detection, use of appropriate therapies, length of stay in the emergency department (ED) and costs of treatment
- Patient outcomes

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

These National Academy of Clinical Biochemistry (NACB) guidelines were developed rigorously; however it was possible to include only papers published in the English language. The specified method for developing the evidence base for recommendations listed involved use of PubMed, EMBASE, and other databases that were not necessarily published. Systematic methods were used whenever available; searches were first set to be sensitive to avoid missing papers of possible interest, and then narrowed to sort through the literature in order to enhance specificity. The writing group contacted recognized experts to assure that important evidence had not been missed.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Weight of Evidence

A - Data derived from multiple randomized or appropriately designed clinical trials that involved large numbers of patients

B - Data derived from a limited number of randomized or appropriately designed trials that involved small numbers of patients or from careful analyses of observational registries

C - Expert Consensus was the primary basis for the recommendation

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The National Academy of Clinical Biochemistry's (NACB) Laboratory Medicine Practice Guidelines (LMPG) for use of cardiac markers in coronary artery diseases were published in July of 1999. Since production of this initial document, numerous published studies and presented data have added significantly to the knowledge base for cardiac biomarkers. This increased knowledge has substantially expanded the scope of recommendations for cardiac biomarker utilization since the 1999 document, and in particular has required the inclusion of recommendations regarding biomarkers that extend beyond myocardial necrosis. Toward addressing these advances and their impact on biomarker utilization in clinical practice, the NACB appointed a chair and members of a LMPG committee that was charged with the overall objective of revising and extending the earlier recommendations by establishing modern guidelines for Utilization of Biomarkers in Acute Coronary Syndrome and Heart Failure. This LMPG is aimed at providing analytical and clinical guidance for the measurement and interpretation of cardiac biochemical markers of acute coronary syndromes (ACS), heart failure and point-of-care measurement and logistics of providing ACS biomarker data for patient care; guidance for interpretation of biomarkers in etiologies other than ACS and Heart Failure is included as well.

These guidelines and their recommendations are structured into six chapters that include Chapter 1: Clinical Utilization of Biomarkers in Acute Coronary Syndromes (ACS); Chapter 2: Analytical Issues of ACS Biomarkers; Chapter 3: Clinical Utilization of Biomarkers of Heart Failure; Chapter 4: Analytical Issues of Heart Failure Biomarkers; Chapter 5: Point of Care Testing and Logistics; and Chapter 6: Cardiac Biomarkers and Other Etiologies. Each chapter was spearheaded by a writing group, which was a subset of the overall committee. In addition, other ad hoc expertise contributed to the writing group of some subsections and chapters to optimize the content and quality of the guidelines. The "questions" for each chapter are in the form of issues addressed and specified in the organization of each individual chapter. The chapter design of the guidelines was used to facilitate

finding guidance by users; this format was also used, in part, to provide an easy and focused procedure for updating the guidelines in the future. Also, the chapter design allowed publication of sections in appropriate laboratory medicine and clinical specialty journals.

Stakeholder involvement in development and refinement of these guidelines was substantial. The guideline team was comprised of laboratory medicine, ACS cardiology experts, and heart failure cardiology experts. As these guidelines target acutely ill patients, Emergency Medicine stakeholders were represented by a specialist; it is also noteworthy that all of the laboratory professionals and cardiology experts on the guideline committee have substantial interaction, knowledge, and publications in the area of laboratory and clinical medicine in the Emergency Medicine environment.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Modified American College of Cardiology/American Heart Association Classifications: Summary of Indications

Class I: Conditions for which there is evidence and/or general agreement that a given laboratory procedure or treatment is useful and effective.

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a laboratory procedure or treatment.

> **Class IIa**: Weight of evidence/opinion is in favor of usefulness/efficacy.
>
> **Class IIb**: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that the laboratory procedure/treatment is not useful/effective and in some cases may be harmful.

COST ANALYSIS

Guideline developers reviewed published cost analyses. Point of care (POC) testing has been reported to reduce costs and total emergency department (ED) length of stay.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Stakeholder involvement in development and refinement of these guidelines was substantial. To further enhance stakeholder input, draft revisions of the Guidelines were prepared and placed for comment on the National Academy of Clinical Biochemistry (NACB) World Wide Web site

(http://www.aacc.org/AACC/members/nacb/LMPG/OnlineGuide/DraftGuidelines/BioHearFailure/). The draft Laboratory Medicine Practice Guidelines (LMPG) and suggested revisions were also presented for public and stakeholder comment at the October 2004 Arnold O. Beckman Conference titled *Cardiac Markers: Establishing Guidelines and Improving Results*. Refer to Table 1 of the Preamble to the original guideline document for a list of the various stakeholder groups that agreed to examine the documents and were represented at the conference.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the weight of evidence (A-C) and the summary of indications (Classes I, II, IIa, IIb, III) are presented at the end of the "Major Recommendations" field.

Note from the National Academy of Clinical Biochemistry (NACB) and the National Guideline Clearinghouse (NGC)*: The Laboratory Medicine Practice Guidelines (LMPG) for utilization of biochemical markers in acute coronary syndromes and heart failure* have been divided into individual summaries. In addition to the current summary, the following are available:

- Chapter 1: Clinical characteristics and utilization of biochemical markers in acute coronary syndromes
- Chapter 2: Analytical issues for biochemical markers of acute coronary syndromes
- Chapter 3: Clinical utilization of cardiac biomarker testing in heart failure
- Chapter 4: Analytical issues for biomarkers of heart failure
- Chapter 6: Use of cardiac troponin and B-type natriuretic peptide or N-terminal proB-type natriuretic peptide for etiologies other than acute coronary syndromes and heart failure

Organization of Cardiac Biomarker Services

Collaboration on Providing Cardiac Biomarker Measurements

Recommendations for Stakeholder Collaboration on Cardiac Biomarker Services

Class I

1. Members of emergency departments, divisions of cardiology, primary care physicians, hospital administrations, and clinical laboratories should work collectively to develop an accelerated protocol for the use of biochemical markers in the evaluation of patients with possible acute coronary syndrome (ACS). **(Level of Evidence: C)**
2. Members of emergency departments, divisions of cardiology, primary care physicians, hospital administrations, and clinical laboratories should work collaboratively to use quality-assurance measures, evidence-based guidelines, and monitoring to reduce medical error and improve the treatment of patients with possible ACS. **(Level of Evidence: C)**

Class IIa

1. For simplicity, protocols for cardiac biomarker testing should apply to either the facilitated diagnosis or the rule-out of acute myocardial infarction (AMI) in the Emergency Department (ED) or to routine diagnosis from other areas of the hospital, should a patient develop symptoms consistent with ACS while hospitalized. **(Level of Evidence: C)**

Responsibility for Providing and Monitoring Cardiac Biomarker Measurements

Class I

1. Laboratory personnel must be involved in selection of devices, the training of individuals to perform the analysis, the maintenance of point-of-care (POC) equipment, the verification of the proficiency of operators on a regular basis, and assuring compliance and documentation of all requirements by regulatory agencies. **(Level of Evidence: C)**
2. The multidisciplinary team involved in cardiac biomarker testing must include personnel knowledgeable about local reimbursement. Vendors should work with customers to help optimize cost-effective provision of biomarker testing. **(Level of Evidence: B)**

Logistics of Cardiac Biomarker Services

Cardiac Biomarker Testing: Preanalytical, Analytical, and Postanalytical Aspects

Recommendations for cardiac biomarker measurements

Class I

1. The specimen of choice for analysis of biochemical markers of cardiac injury is plasma or anticoagulated whole blood to facilitate a more rapid turnaround time for testing. **(Level of Evidence: C)**
2. For routine clinical practice, blood collections should be referenced relative to the time of presentation to the emergency department and (when available) the reported time of chest pain onset. **(Level of Evidence: C)**
3. The laboratory should perform cardiac marker testing with a turnaround time of 1 hour, optimally 30 minutes, or less. The turnaround time is defined as the time from blood collection to the reporting of results. **(Level of Evidence: B)**
4. Performance specifications and characteristics for central laboratory and POC platforms must not differ. **(Level of Evidence: C)**

Class IIa

1. Institutions that cannot consistently deliver cardiac marker turnaround times of approximately 1 hour should implement POC testing devices. **(Level of Evidence B)**

Class IIb

1. While it is recognized that qualitative systems do provide useful information, it is recommended that POC systems provide quantitative results. **(Level of Evidence: C)**

Evolving Technology in Cardiac Biomarkers

Process for Adapting Evolving Biomarker Technology

Recommendations for Adapting Evolving Technologies

Class I

1. Early in the process, manufacturers are encouraged to seek assistance and provide support to professional organizations such as the American Association for Clinical Chemistry (AACC) or International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) to develop committees for the standardization of new analytes. These organizations will determine the need for analyte standardization based on the potential clinical importance of the marker and gather the necessary scientific expertise for the formation of a standardization committee. **(Level of Evidence: C)**

Definitions:

Weight of Evidence

A - Data derived from multiple randomized or appropriately designed clinical trials that involved large numbers of patients

B - Data derived from a limited number of randomized or appropriately designed trials that involved small numbers of patients or from careful analyses of observational registries

C - Expert Consensus was the primary basis for the recommendation

Summary of Indications

Class I: Conditions for which there is evidence and/or general agreement that a given laboratory procedure or treatment is useful and effective.

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a laboratory procedure or treatment.

Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.

Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that the laboratory procedure/treatment is not useful/effective and in some cases may be harmful.

CLINICAL ALGORITHM(S)

A clinical algorithm is provided that illustrates time point options available to define turnaround time (TAT).

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Quality assurance activities improve patient outcomes.
- The introduction of point-of-care (POC) testing has been reported to reduce costs and total emergency department (ED) length of stay. For those patients who are ruled out for acute coronary syndrome (ACS), it is expected that rapid turnaround times (TATs) for laboratory data will lead to expedited patient discharge and a reduction in overall hospital costs.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The materials in this publication represent the opinions of the authors and committee members, and do not represent the official position of the National Academy of Clinical Biochemistry (NACB). The National Academy of Clinical Biochemistry is the academy of the American Association for Clinical Chemistry.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Starrow AB, Apple FS, Wu AH, Jesse RL, Francis GS, Christenson RH, Cannon CP, Morrow DA, Newby LK, Ravkilde J, Tang W. National Academy of Clinical Biochemistry laboratory medicine practice guidelines: point of care testing, oversight, and administration of cardiac biomarkers for acute coronary syndromes. Point Care 2007 Dec;6(4):215-22.

Storrow AB, Apple FS, Francis GS. National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines: point of care testing, oversight and administration of cardiac biomarkers for acute coronary syndromes. Washington (DC): National Academy of Clinical Biochemistry; 2007. 9 p. [86 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Jul (revised 2007 Jan)

GUIDELINE DEVELOPER(S)

National Academy of Clinical Biochemistry - Professional Association

SOURCE(S) OF FUNDING

National Academy of Clinical Biochemistry

GUIDELINE COMMITTEE

The National Academy of Clinical Biochemistry

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

National Academy of Clinical Biochemistry (NACB) Writing Group Members: Alan B. Storrow, MD, Section Leader; Fred S. Apple, PhD; Alan H.B. Wu, PhD; Robert L. Jesse, MD, PhD; Gary S. Francis, MD; Robert H. Christenson, PhD

NACB Committee Members: Robert H. Christenson, *Chair*, University of Maryland School of Medicine, Baltimore, Maryland, USA; Fred S. Apple, Hennepin County Medical Center and University of Minnesota, Minneapolis, Minnesota, USA; Christopher P. Cannon, Brigham and Women's Hospital, Boston, Massachusetts, USA; Gary S. Francis, Cleveland Clinic Foundation, Cleveland, Ohio, USA; Robert L. Jesse, Medical College of Virginia, Richmond, Virginia, USA; David A. Morrow, Brigham and Women's Hospital, Boston, Massachusetts, USA; L. Kristin Newby, Duke University Medical Center, Durham, North Carolina, USA; Jan Ravkilde, Aarhus University Hospital, Aarhus, Denmark; Alan B. Storrow, Vanderbilt University, Nashville, Tennessee, USA; W. H. Wilson Tang, Cleveland Clinic Foundation, Cleveland, Ohio, USA; Alan H. B. Wu, San Francisco General Hospital and University of California at San Francisco, San Francisco, California, USA

Ad Hoc members of the committee for selected sections: Allan S. Jaffe, Mayo Clinic, Rochester, Minnesota, USA; Alan S. Maisel, University of California at San Diego, San Diego, California, USA; Mauro Panteghini, University of Milan, Milan, Italy

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Other than modest funding from the National Academy of Clinical Biochemistry/American Association for Clinical Chemistry (NACB/AACC), development of these guidelines was a volunteer activity. Thus the guidelines are editorially independent from any funding body.

All potential conflicts of interest for the NACB guidelines committee and ad hoc members of the writing committees are listed at the following: http://www.aacc.org/AACC/members/nacb/LMPG/OnlineGuide/PublishedGuidelines/ACSHeart/heartpdf.htm.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Wu AH, Apple FS, Gibler WB, Jesse RL, Warshaw MM, Valdes R Jr. National Academy of Clinical Biochemistry Standards of Laboratory Practice: recommendations for the use of cardiac markers in coronary artery diseases. Clin Chem 1999 Jul;45(7):1104-21. [119 references] PubMed

GUIDELINE AVAILABILITY

Electronic copies: Available from the National Academy of Clinical Biochemistry (NACB) Web site.

Print copies: National Academy of Clinical Biochemistry publications are available through American Association for Clinical Chemistry (AACC) Press. To make a purchase or request a catalog, contact AACC Customer Service at 202-857-0717 or custserv@aacc.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Preamble. National Academy of Clinical Biochemistry laboratory medicine practice guidelines for utilization of biochemical markers in acute coronary syndromes and heart failure. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2007. p. 1-3.

Electronic copies: Available from the National Academy of Clinical Biochemistry (NACB) Web site.

Print copies: National Academy of Clinical Biochemistry publications are available through American Association for Clinical Chemistry (AACC) Press. To make a purchase or request a catalog, contact AACC Customer Service at 202-857-0717 or custserv@aacc.org.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on March 12, 2008. The information was verified by the guideline developer on April 2, 2008.

COPYRIGHT STATEMENT

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC

Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion.aspx .

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

Date Modified: 9/29/2008